

**REMARKS**

In the present Application, Claims 1, 3, 4, 5, 6, 7, 16, 17, 18, 19 and 20 have been cancelled, and new Claims 23-25 have been added. As such, Claims 10, 11, 13-15, and 23-25 are currently pending. The Examiner's objections and rejections are as follows:

- (I) The Examiner indicated that two IDS references could not be located;
- (II) Claims 1, 3-7, 10, 11, and 13-20 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Rees et al. 6,197,330 (or 5,972,332; 6,440,452, or 6,399,898) in view of Dionne et al. (5,786,216) and Shapiro et al. (6,425,918); and
- (III) Claims 1, 3-7, 10, 11, and 13-20 were rejected under the judicially created doctrine of obviousness-type double patenting.

Applicant believes the following remarks traverse the Examiner's objections and rejections.

**I. IDS References**

The Examiner indicated that two references (Ref. 5 and Ref. 29 from the 1449) have not been considered because they could not be located. Reference 5 is U.S. Pat. 5,269,917 which is attached to this communication at Tab A. Reference 29 is a book (Goeddel, Gene Therapy Expression Technology: Methods in Enzymology 185, Academic Press, San Diego, CA, 1990). If the Examiner believes this reference is necessary in order to examine the present Application, applicants are willing to locate this book and send it to the Examiner.

**II. No *Prima Facie* Case of Obviousness has been Established**

The Examiner rejected Claims 1, 3-7, 10, 11, and 13-20 under 35 U.S.C. 103(a) as being allegedly unpatentable over Rees et al. 6,197,330 (or 5,972,332; 6,440,452, or 6,399,898) in view of Dionne et al. (5,786,216) and Shapiro et al. (6,425,918). Applicant respectfully disagrees with this rejection.

While the Examiner has asserted a *prima facie* case of obviousness against the claims that require the cells to be injected (i.e. Claims 1, 3-7, and 16-20), the Examiner has not made any arguments about the claims that recite that the cells migrate into the enclosure (i.e. Claims 10, 11, and 13-15). Therefore, while Applicant disagrees with the Examiner's rejection of Claims 1,

3-7 and 16-20, and submit that the Examiner has not established a *prima facie* case of obviousness, these claims have been cancelled for business reasons, in order to further the prosecution of the present Application, yet without acquiescing to the Examiner's rejection, while explicitly reserving the right to prosecute the original claims (or similar claims) in the future. As such, only claims that recite that the cells migrate into the enclosure are now pending (e.g. Claims 10, 11, and 13-15).

The Examiner rejected Claims 10, 11, and 13-15 as obvious, but the Examiner did not attempt to explain how the cited art (Rees et al., Shapiro et al. and Dionne et al) applies to these claims. As such, the Examiner has not met his initial burden of establishing (let alone alleging) a *prima facie* case of obviousness. Therefore, Applicant submits that these claims should be allowed. Applicants further submits that the Examiner could not establish a *prima facie* case of obviousness with the cited art against these claims (e.g. the combined art does not teach immersing a sealed solid support containing enclosure in a culture of viable cells), and therefore Claims 10, 11, and 13-15 should be passed to allowance.

Applicant also notes that new Claims 23-25 have been added. Claim 23 further limits Claim 10 by reciting that the viable cells are foreskin derived cells. Claim 24 mirrors Claim 10 and further recites heat-sterilizing and freezing steps, while Claim 25 recites that the viable cells of Claim 24 are human foreskin cells. Applicant submits that, at a minimum, these new claims should be passed to allowance.

### **III. Double Patenting Rejection**

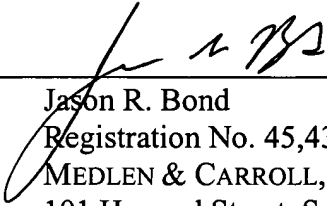
The Examiner rejected Claims 1, 3-7, 10, 11, and 13-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Pat. 6,197,330 or claims 1-6 of U.S. Pat. 5,972,332 or claims 1-22 of U.S. Pat. 6,440,452 or claims 1-21 of U.S. Pat. 6,299,898 in view of Dionne et al. and Shapiro et al. Applicants disagree with this rejection.

The Examiner's double patenting rejection, again, only address claims where the cells are injected into the enclosure, and does not address claims where the cells migrate into the enclosure. As only claims that recite that the cells migrate into the enclosure are now pending, which have not been addressed by the Examiner, this rejection should be withdrawn.

**CONCLUSION**

For the reasons set forth above, it is respectfully submitted that Applicant's claims should be passed to allowance. If a telephone interview would aid in the prosecution of this Application, Applicant encourages the Examiner to call the undersigned collect at 608-218-6900.

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